REMARKS

I. STATUS OF CLAIMS

Claims 1 and 4-8 are currently pending. With this Reply, claims 1 and 4-6 are amended. Support for the above amendments can be found in the specification at least on pages 2, 3, 5, and 6. No new matter is added by this Reply.

II. EXAMINER INTERVIEW

Applicants wish to thank Examiner Jagoe for the interview conducted on October 5, 2005. This interview provided a good opportunity to discuss the pending application in view of the cited prior art.

III. REJECTION UNDER 35 U.S.C. § 103

The Office rejected claims 1 and 4-7 under 35 U.S.C. § 103(a) as unpatentable over Buzas et al. RO 92436 ("Buzas") in view of U.S. Patent No. 5,883,115 to Santus et al. ("Santus"). Office Action at page 3. Specifically, the Office asserts that Buzas teaches a composition comprising a carbonic anhydrase inhibitor and a beta blocker such as pindolol to treat gastritis, gastro-duodenitis, and gastro-duodenal ulcers. *Id.* Under the Office's rationale, Buzas is deficient in that it does not teach S(-)pindolol and thus, Santus remedies such deficiency by teaching that S(-) pindolol is the most active eutomer . *Id.* Accordingly, the Office contends that the combination of these cited references establishes a *prima facie* case of obviousness over the pending claims. *Id.* Applicants respectfully disagree for the reasons of record and for the additional reasons provided below.

Initially, Buzas is specifically directed to "the treatment of gastritis, gastroduodenitis, and gastric and duodenal ulcers used to *reduce gastric acid secretion*." Buzas at page 2 (emphasis added); *see also*, Buzas at Abstract. In fact, Buzas' stated objective is "to obtain a *synergistic* pharmaceutical composition for the treatment of gastritis, gastroduodenitis, and gastric and duodenal ulcers, through v*asomotor impulse regulation of gastric secretions*." *Id.* at page 2 (emphasis added). To this end, Buzas discloses a pharmaceutical composition comprising a carbonic anhydrase inhibitor and a beta-adrenergic blocker having a weight ratio of carbonic anhydrase inhibitor to beta-blocker of 1.37 to 231. *Id.*

Demonstrating the synergistic interaction between carbonic anhydrase and beta-adrenergic blockers, Buzas examined *in vivo* administration of some beta-adrenergic blockers alone, including pindolol, on gastric acid secretion and carbonic anhydrase activity. *Id.* at Table 3, page 8. Buzas observed that administration of "some beta-adrenergic blockers . . . leads to *slightly* decreased gastric acid secretion parameters and carbonic anhydrase activity." *Id.* at page 8 (emphasis added). Additional data presented with respect to the administration of carbonic anhydrase inhibitors dosed alone demonstrates further decreases in hydrochloric acid and carbonic anhydrase secretions. *Id.* at pages 8-12. The combination of beta-adrenergic blockers and carbonic anhydrase inhibitors, however, results in decreases in hydrochloric acid and carbonic anhydrase secretions greater than the individual compounds dosed alone, i.e., synergistic. *Id.* at page 12, Table 9. All of Buzas' testing and comparisons center around this primary objective, i.e., "reduc[ing] gastric acid secretion[s]."

In stark contrast, the present application is directed to treating gastrointestinal diseases, wherein the gastrointestinal disease lacks a structural or biochemical abnormality. Applicants Specification at least on page 3. The gastrointestinal disorders recited in amended claim 1 are inapposite to those disorders related to gastric acid secretion, as exemplified in Buzas, such as a peptic ulcer (i.e., a gastric ulcer on page 2 of Buzas).

Gastric acid secretions and the resulting wearing away of the gastrointestinal lining (a structural symptom) can be diagnosed by esophagogastroduodenscopy or upper endoscopy (the visualization of various parts of the gastrointestinal tract), i.e. using conventional diagnostic tools. Even though Buzas presents data of pindolol administered alone, it is directed to suppressing gastric acid and carbonic anhydrase, i.e., a biochemical explanation, and thus, is directed to a different therapeutic use than presently claimed in the amended claims. Moreover, no evidence in Buzas suggests that data on gastric acid secretions and carbonic anhydrase could be interpreted to treat gastrointestinal disorders that lack a structural or biochemical abnormality; instead, as suggested in the present specification at least on page 3, the gastrointestinal disorders recited in amended claim 1 presume the absence of a structural or biochemical abnormality.

In conclusion, the secondarily cited teachings of Santus do not remedy these deficiencies. Rather, the Office relies on Santus for its alleged teaching that "S(-) pindolol is the most active eutomer (enantiomer) . . . ." Office Action at pages 3 and 4. In fact, Santus lacks any discussion on the effects of S(-) pindolol. Santus at Col. 6, ll.

45-67, Table II. Without such a teaching, there is not only a lack of motivation for the combination of the cited art references, but their asserted combination fails, *inter alia*, to teach all of the recited claim limitations. *See* M.P.E.P. § 2143. Accordingly, a *prima facie* case of obviousness has not been established, and Applicants respectfully request the withdrawal of the rejection.

IV. CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration of this application and the timely allowance of the pending claims.

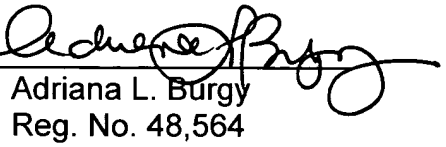
If the Examiner believes that a telephone conference could be useful in resolving any outstanding issues, she is respectfully urged to contact Applicants' undersigned counsel at 202.408.4345.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: November 7, 2005

By: 
Adriana L. Burgy
Reg. No. 48,564